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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/807,665 | 06/28/2001 | Carlos F. Barbas | TSRI 645.1 | 2213 |
| 26621 | 7590 | 06/08/2004 | EXAMINER | |
| THE SCRIPPS RESEARCH INSTITUTE OFFICE OF PATENT COUNSEL, TPC-8 10550 NORTH TORREY PINES ROAD LA JOLLA, CA 92037 | | | | CARLSON, KAREN C |
| ART UNIT | | PAPER NUMBER | | |
| | | 1653 | | |

DATE MAILED: 06/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-------------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/807,665 | BARBAS, CARLOS F. |
| | Examiner | Art Unit |
| | Karen Cochrane Carlson, Ph.D. | 1653 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 08 March 2004.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-21 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-21 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>10/8/2002</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

Applicant's election with traverse of Invention 41, SEQ ID NO: 41 in the paper filed March 8, 2004 is acknowledged. The traversal is on the ground(s) that Applicants urge that the sequences listed in amended Claim 1 are unified by the structure RSDXLV(R/K). The amino acid sequence of elected SEQ ID NO: 41 is KSADLKR and does not share this structural sequence. Therefore, the argument that there is a single structure to be searched for all of the sequences listed in Claim 1 is not persuasive. The polynucleotide encoding SEQ ID NO: 41 have been rejoined because search of the polypeptide resulted in art for the encoding polynucleotide and therefore did not pose an undue burden on the Examiner.

The restriction requirement is made FINAL.

The IDS filed April 27, 2003 did not have a PTO-1449 attached, or references attached.

Claim 4 has been canceled. Claims 1-3 and 4-21 are currently pending and are under examination with regard to SEQ ID NO: 41.

Priority is set to October 16, 2004.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 28-56 of U.S. Patent No. 6,242,568. Although the conflicting claims are not identical, they are not patentably distinct from each

other because the claims are overlapping such that one set of claims are obvious over the other set of claims.

Claims 1-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-39, 53 of U.S. Patent No. 6,140,466. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are overlapping such that one set of claims are obvious over the other set of claims.

Claims 20 and 21 provide for the use of zinc finger proteins containing SEQ ID NO: 41, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 20 and 21 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These Claims are drawn to non-elected subject matter and therefore the claims are indefinite because it is not clear what the Applicants regard to be their elected invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-3 and 5-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Barbas et al. (USP 6,242,568, issued June 5, 2001 and having a 102(e) date of December 30, 1996).

Barbas et al. teach C7 zinc finger nucleotide binding polypeptide containing instant SEQ ID NO: 41 (KSADLKR) in Figure 15 and in patent SEQ ID NO: 42 at amino acids 20-26 (Claim 1). The nucleotide sequence encoding patent SEQ ID NO: 42 is shown as SEQ ID NO: 41 (Claim 10).

In Example 13, at col. 50, line 5-6, Barbas et al. teach that proteins containing 2-12 copies of C7 finger protein were constructed (Claims 2, 3). The C7 fingers were linked with TGEKP (which is instant SEQ ID NO: 111; see col. 49, line 21; Claim 5). Barbas et al. state that these multiple copy C7 zinc fingers have specificity for predicted targets, which are nucleotide sequences (Claim 6, 7). Because Barbas et al. teach that this sequence is a fusion protein, then nucleic acid encoding the multiple copy C7 was inherently in hand (Claim 11), placed into an expression vector (Claim 12, 13) for recombinant production of the multiple copy C7 zinc finger protein.

At Col. 49, line 4, Barbas et al. teach (C7)₆-Jun, wherein Jun is a leucine zipper (Claims 8, 9).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-7 and 14-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barbas et al. (USP 6,242,568, issued June 5, 2001 and having a 102(e) date of December 30, 1996).

The teachings of Barbas et al. are set forth above regarding Claims 2-7.

Additionally, Barbas et al. teach binding the of zinc finger proteins to a nucleotide sequence, Barbas et al. do not expressly teach a process for regulating the activity of nucleotide sequences that containing SEQ ID NO: 123 (see patent SEQ ID NO: 37, and Example 12, for example) with zinc fingers containing SEQ ID NO: 41 such as containing 2-12 copies of C7 finger protein or (C7)₆-Jun. At Col. 5, line 52 to Col. 6, line 11, Barbas et al. suggest that the zinc finger proteins should be used to modulate the function of the cellular nucleotide sequences, wherein the cellular nucleotide sequences can be located in exons or promoters. Barbas et al. exemplifies Zf1-3 repression of T7 RNA polymerase in Figure 5.

Additionally, Barbas et al. do not explicitly teach medicaments comprising containing 2-12 copies of C7 finger protein or (C7)₆-Jun. At Col. 7, line 56 to Col. 8, line 54, Barbas et al. state that pharmaceutical compositions comprising zinc fingers are useful in therapeutic methods because these proteins would have reduced side effects when compared to other therapeutic agents.

It would have been obvious to a person having ordinary skill in the art to regulate nucleotide sequences having SEQ ID NO: 23 by exposing these sequences to proteins containing 2-12 copies of C7 finger protein or (C7)₆-Jun because Barbas et al. suggests to and motivates one skilled in the art that these zinc finger proteins are useful for regulating cellular nucleotide

sequences. Such activity would be predictable because Barbas et al. exemplify this method with other zinc finger polypeptides (Claim 14-18).

It would have been obvious to a person having ordinary skill in the art to place the proteins containing 2-12 copies of C7 finger protein or (C7)₆-Jun into a pharmaceutical composition because Barbas et al. suggest and motivate one skilled in the art to make pharmaceutical compositions of zinc finger proteins for therapeutic effects (Claims 19-22).

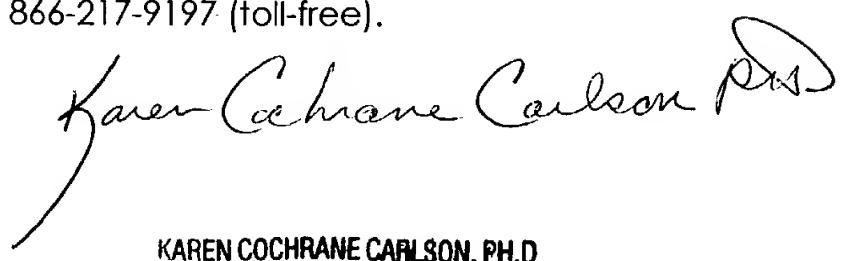
USP 6,140,466 (priority to at least May 27, 1997) is the same up through Example 13 of USP 6,242,568 and would be applied in the same manner as 6,242,568.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER